DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 055

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 055" (Recognition List Number: 055), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may

not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2004-N-0451 for "Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 055." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 055.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a

written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

An electronic copy of Recognition List Number: 055 is available on the internet at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. See section IV for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 055 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 055" to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903

New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301-796-6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8144.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301-796-6287, CDRHStandardsStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In the *Federal Register* of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." The guidance describes how FDA has implemented its standards recognition program and is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. Modifications to the initial list of recognized standards, as published in the *Federal Register*, can be accessed at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains on its website hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards, available at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents. Additional information on the Agency's Standards and

Conformity Assessment Program is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

II. Modifications to the List of Recognized Standards, Recognition List Number: 055

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA is using the term "Recognition List Number: 055" to identify the current modifications.

In table 1, FDA describes the following modifications: (1) the withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 055.

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
A. Anesthesiology			
1-79	1-147	ISO 26825 Second edition 2020-10 Anaesthetic and respiratory equipment--User-applied labels for syringes containing drugs used during anaesthesia--Colours, design and performance.	Withdrawn and replaced with newer version.
1-102	1-148	ISO 80601-2-69 Second edition 2020-11 Medical electrical equipment--Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment.	Withdrawn and replaced with newer version.
1-123	1-149	ISO 7376 Third edition 2020-08 Anaesthetic and respiratory equipment--Laryngoscopes for tracheal intubation.	Withdrawn and replaced with newer version.
1-125	1-150	ISO 8836 Fifth edition 2019-12 Suction catheters for use in the respiratory tract.	Withdrawn and replaced with newer version.
1-146		ISO 80601-2-12 Second edition 2020-02 Medical electrical equipment--Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.	Transition period extended.
B. Biocompatibility			
2-119	2-277	ASTM F813-20 Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices.	Withdrawn and replaced with newer version.

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
2-122	2-278	ASTM F719-20 ε1 Standard Practice for Testing Materials in Rabbits for Primary Skin Irritation.	Withdrawn and replaced with newer version.
2-124	2-279	ASTM F750-20 Standard Practice for Evaluating Acute Systemic Toxicity of Material Extracts by Systemic Injection in the Mouse.	Withdrawn and replaced with newer version.
2-133	2-280	ASTM F1408-20a Standard Practice for Subcutaneous Screening Test for Implant Materials.	Withdrawn and replaced with newer version.
2-167	2-281	ISO 10993-19 Second edition 2020-03 Biological evaluation of medical devices--Part 19: Physico-chemical, morphological and topographical characterization of materials.	Withdrawn and replaced with newer version.
2-205	2-282	ISO 14155 Third edition 2020-07 Clinical investigation of medical devices for human subjects--Good clinical practice.	Withdrawn and replaced with newer version.
2-214	2-283	ASTM F619-20 Standard Practice for Extraction of Materials Used in Medical Devices.	Withdrawn and replaced with newer version.
2-269	2-284	USP 43-NF38:2020 <87> Biological Reactivity Test, In Vitro--Direct Contact Test.	Withdrawn and replaced with newer version.
2-270	2-285	USP 43-NF38:2020 <87> Biological Reactivity Test, In Vitro--Elution Test.	Withdrawn and replaced with newer version.
2-271	2-286	USP 43-NF38:2020 <88> Biological Reactivity Tests, In Vivo.	Withdrawn and replaced with newer version.
2-272	2-287	USP 43-NF38:2020 <151> Pyrogen Test (USP Rabbit Test).	Withdrawn and replaced with newer version.
C. Cardiovascular			
No new entries at this time.			
D. Dental/Ear, Nose, and Throat (ENT)			
4-92	4-264	ANSI/ADA Standard No. 88--2019 Dental Brazing Alloys.	Withdrawn and replaced with newer version.
4-243		ISO 10271 First edition 2001-06 Dental metallic materials--Corrosion test methods.	Withdrawn.
4-245	4-265	ISO 10271 Third edition 2020-08 Dentistry--Corrosion test methods for metallic materials.	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
5-76	5-131	IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment--Part 1-8: General requirements for basic safety and essential performance--Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.	Withdrawn and replaced with newer version.
5-89	5-132	IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment--Part 1-6: General requirements for basic safety and essential performance--Collateral standard: Usability.	Withdrawn and replaced with newer version.
5-115	5-133	ISO 80369-7 Second edition 2021 Small-bore connectors for liquids and gases in healthcare applications--Part 7: Connectors for intravascular or hypodermic applications.	Withdrawn and replaced with newer version.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19-8	19-36	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral Standard: Electromagnetic disturbances--Requirements and tests.	Withdrawn and replaced with newer version.

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
19-9	19-37	IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment--Part 1-10: General requirements for basic safety and essential performance--Collateral Standard: Requirements for the development of physiologic closed-loop controllers.	Withdrawn and replaced with newer version.
19-14	19-38	IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment--Part 1-11: General requirements for basic safety and essential performance--Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	Withdrawn and replaced with newer version.
19-15	19-39	IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment--Part 1-12: General requirements for basic safety and essential performance--Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6-11		ISO 594-1 First edition 1986-06-15 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment--Part 1: General requirements.	Withdrawn. See 5-133.
6-129		ISO 594-2 Second edition 1998-09-01 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment--Part 2: Lock fittings.	Withdrawn. See 5-133.
6-180	6-448	ASTM F2407-20 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities.	Withdrawn and replaced with newer version.
6-339	6-449	ASTM F1169-19 Standard Consumer Safety Specification for Full-Size Baby Cribs.	Withdrawn and replaced with newer version.
6-340		ASTM F2710-13 Standard Consumer Safety Performance Specification for Commercial Cribs.	Withdrawn.
6-387	6-450	IEC 60601-2-50 Ed. 3.0 2020-09 Medical electrical equipment--Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment.	Withdrawn and replaced with newer version.
6-428	6-451	USP 43-NF38:2020 Sodium Chloride Irrigation.	Withdrawn and replaced with newer version.
6-429	6-452	USP 43-NF38:2020 Sodium Chloride Injection.	Withdrawn and replaced with newer version.
6-430	6-453	USP 43-NF38:2020 Nonabsorbable Surgical Suture.	Withdrawn and replaced with newer version.
6-431	6-454	USP 43-NF38:2020 <881> Tensile Strength.	Withdrawn and replaced with newer version.
6-432	6-455	USP 43-NF38:2020 <861> Sutures--Diameter.	Withdrawn and replaced with newer version.
6-433	6-456	USP 43-NF38:2020 <871> Sutures--Needle Attachment.	Withdrawn and replaced with newer version.
6-434	6-457	USP 43-NF38:2020 Sterile Water for Irrigation.	Withdrawn and replaced with newer version.
6-435	6-458	USP 43-NF38:2020 Heparin Lock Flush Solution.	Withdrawn and replaced with newer version.
6-436	6-459	USP 43-NF38:2020 Absorbable Surgical Suture.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
7-101		CLSI H51-A Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline.	Withdrawn.
7-112	7-299	CLSI POCT14 2nd Edition Point-of-Care Coagulation Testing and Anticoagulation Monitoring.	Withdrawn and replaced with newer version.
7-131		CLSI I/LA18-A2 (Replaces I/LA18-A) Specifications for Immunological Testing for Infectious Diseases; Approved Guideline--Second Edition.	Withdrawn.
7-135		CLSI H44-A2 (Replaces H44-A) Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline--Second Edition.	Withdrawn.
7-142		CLSI GP43-A4 (Formerly H11-A4) Procedures for the Collection of Arterial Blood Specimens; Approved Standard--Fourth Edition.	Withdrawn.
7-146		CLSI M06-A2 Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard--Second Edition.	Withdrawn.
7-164		CLSI GP28-A (Replaces GP28-P) Microwave Device Use in the Histology Laboratory; Approved Guideline.	Withdrawn.
7-173		CLSI C44-A (Replaces C44-P) Harmonization of Glycohemoglobin Measurements; Approved Guideline.	Withdrawn.
7-191	7-300	CLSI MM13 2nd Edition Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods.	Withdrawn and replaced with newer version.
7-203	7-301	CLSI GP42 7th Edition Collection of Capillary Blood Specimens.	Withdrawn and replaced with newer version.
7-211	7-302	CLSI C34 4th Edition Sweat Testing: Specimen Collection and Quantitative Chloride Analysis.	Withdrawn and replaced with newer version.
7-217	7-303	CLSI M60 2nd Edition Performance Standards for Antifungal Susceptibility Testing of Yeast.	Withdrawn and replaced with newer version.
7-261	7-304	CLSI M23 5th Edition Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters.	Withdrawn and replaced with newer version.
I. Materials			
8-217	8-537	ASTM F620-20 Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition.	Withdrawn and replaced with newer version.
8-223	8-538	ASTM F2759-19 Standard Guide for Assessment of the Ultra-High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices.	Withdrawn and replaced with newer version.
8-338	8-539	ASTM F139-19 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673).	Withdrawn and replaced with newer version.
8-339	8-540	ASTM F1091-20 Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605).	Withdrawn and replaced with newer version.
8-342	8-541	ASTM F1537-20 Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539).	Withdrawn and replaced with newer version.
8-348	8-542	ASTM F138-19 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).	Withdrawn and replaced with newer version.
8-361	8-543	ASTM F755-19 Standard Specification for Selection of Porous Polyethylene for Use in Surgical Implants.	Withdrawn and replaced with newer version.

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
8-395	8-544	ASTM F961-20 Standard Specification for 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035).	Withdrawn and replaced with newer version.
8-416	8-545	ASTM F2977-20 Standard Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants.	Withdrawn and replaced with newer version.
8-417	8-546	ASTM F3044-20 Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants.	Withdrawn and replaced with newer version.
8-421	8-547	ASTM F629-20 Standard Practice for Radiography of Cast Metallic Surgical Implants.	Withdrawn and replaced with newer version.
8-438	8-548	ISO/ASTM 52915 Third edition 2020-03 Specification for additive manufacturing file format (AMF) Version 1.2.	Withdrawn and replaced with newer version.
8-530	8-549	ASTM F3208-20 Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices.	Withdrawn and replaced with newer version.
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
9-40	9-130	ISO 8600-6: Second Edition 2020-09 Endoscopes--Medical endoscopes and endotherapy devices--Part 6: Vocabulary	Withdrawn and replaced with newer version.
M. Ophthalmic			
10-48	10-119	ISO 11979-5 Third edition 2020-09 Ophthalmic implants--Intraocular Lenses--Part 5: Biocompatibility.	Withdrawn and replaced with newer version.
10-63	10-120	ISO/TR 22979 Second Edition 2017-05 Ophthalmic implants--Intraocular Lenses--Guidance on assessment of the need for clinical investigation of intraocular lens design modifications.	Withdrawn and replaced with newer version.
N. Orthopedic			
11-191	11-370	ISO 14879-1 Second edition 2020-07 Implants for surgery--Total knee-joint prostheses--Part 1: Determination of endurance properties of knee tibial trays.	Withdrawn and replaced with newer version.
11-267	11-371	ASTM F2009-20 Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses.	Withdrawn and replaced with newer version.
11-279	11-372	ASTM F2996-20 Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems.	Withdrawn and replaced with newer version.
11-282	11-373	ASTM F1223-20 Standard Test Method for Determination of Total Knee Replacement Constraint.	Withdrawn and replaced with newer version.
11-313	11-374	ISO 7207-2 Second edition 2011-07-01 Implants for surgery--Components for partial and total knee joint prostheses--Part 2: Articulating surfaces made of metal, ceramic and plastics materials [Including AMENDMENT 1 (2016) and AMENDMENT 2 (2020)].	Withdrawn and replaced with newer version.
11-330		ASTM F2028-17 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation.	Extent of recognition.
11-332	11-375	ASTM F2193-20 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System.	Withdrawn and replaced with newer version.
O. Physical Medicine			

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
No new entries at this time.			
P. Radiology			
No new entries at this time.			
Q. Software/Informatics			
No new entries at this time.			
R. Sterility			
14-314	14-550	ANSI/AAMI ST67:2019 Sterilization of health care products--Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile".	Withdrawn and replaced with newer version.
14-361	14-551	ISO 14160 Third edition 2020-09 Sterilization of health care products--Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives--Requirements for characterization, development, validation and routine control of a sterilization process for medical devices.	Withdrawn and replaced with newer version.
14-411	14-552	ISO/ASTM 51818 Fourth edition 2020-06 Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV.	Withdrawn and replaced with newer version.
14-498	14-553	ASTM F2097-20 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products.	Withdrawn and replaced with newer version.
14-519	14-554	ASTM F17-20 Standard Terminology Relating to Primary Barrier Packaging.	Withdrawn and replaced with newer version.
14-534	14-555	USP 43-NF38:2020 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.	Withdrawn and replaced with newer version.
14-535	14-556	USP 43-NF38:2020 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14-536	14-557	USP 43-NF38:2020 <55> Biological Indicators--Resistance Performance Tests.	Withdrawn and replaced with newer version.
14-537	14-558	USP 43-NF38:2020 <1229.5> Biological Indicators for Sterilization.	Withdrawn and replaced with newer version.
14-546	14-559	USP 43-NF38:2020 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14-547	14-560	USP 43-NF38:2020 <71> Sterility Tests.	Withdrawn and replaced with newer version.
14-548	14-561	USP 43-NF38:2020 <85> Bacterial Endotoxins Test.	Withdrawn and replaced with newer version.
S. Tissue Engineering			
15-35		ASTM F2900-11 Standard Guide for Characterization of Hydrogels used in Regenerative Medicine.	Withdrawn.
15-36		ASTM F2383-11 Standard Guide for Assessment of Adventitious Agents in Tissue Engineered Medical Products (TEMPs).	Withdrawn.
15-38		ASTM F2883-11 Standard Guide for Characterization of Ceramic and Mineral Based Scaffolds used for Tissue-Engineered Medical Products (TEMPs) and as Device for Surgical Implant Applications.	Withdrawn.
15-45	15-64	ISO 22442-1 Third edition 2020-09 Medical devices utilizing animal tissues and their derivatives--Part 1: Application of risk management.	Withdrawn and replaced with newer version.
15-46	15-65	ISO 22442-2 Third edition 2020-09 Medical devices utilizing animal tissues and their derivatives--Part 2: Controls on sourcing, collection and handling.	Withdrawn and replaced with newer version.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 055. These entries are of standards not previously recognized by FDA.

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
A. Anesthesiology		
No new entries at this time.		
B. Biocompatibility		
2-288	Biological evaluation of medical devices--Part 15: Identification and quantification of degradation products from metals and alloys.	ISO 10993-15 Second edition 2019-11.
C. Cardiovascular		
3-169	Medical electrical equipment--Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators.	IEC Edition 3.1 2018-02 CONSOLIDATED VERSION.
D. Dental/Ear, Nose, and Throat (ENT)		
4-266	Dentistry--Orthodontic anchor screws.	ISO 19023 First edition 2018-02.
4-267	Dentistry--Elastomeric auxiliaries for use in orthodontics.	ISO 21606 First edition 2007-06.
4-268	Dentistry--Wires for use in orthodontics [Including AMENDMENT 1 (2020)].	ISO 15841 Second edition 2014-08.
4-269	Dentistry--Coupling dimensions for handpiece connectors [Including AMENDMENT 1 (2018)].	ISO 3964 Third edition 11-2016.
4-270	CAD/CAM Abutments in Dentistry.	ADA Technical Report No. 146-2018.
4-271	Dental Cartridge Syringes.	ANSI/ADA Standard No. 34-2013.
4-272	Root Canal Barbed Broaches and Rasps.	ANSI/ADA Standard No. 63-2013.
E. General I (Quality Systems/Risk Management) (QS/RM)		
No new entries at this time.		
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
No new entries at this time.		
G. General Hospital/General Plastic Surgery (GH/GPS)		
	No new entries at this time.	
H. In Vitro Diagnostics (IVD)		
7-305	In vitro diagnostic medical devices--Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples.	ISO 17511 Second edition 2020-04.
I. Materials		
8-550	Standard Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants.	ASTM F2181-20.
8-551	Standard Practice for Digital Radiography of Cast Metallic Implants.	ASTM F2895-20.
8-552	Guide for Additive manufacturing--Installation/Operation and Performance Qualification (IQ/OQ/PQ) of Laser-Beam Powder Bed Fusion Equipment for Production Manufacturing New publication.	ASTM F3434-20.
8-553	Additive manufacturing--Material extrusion-based additive manufacturing of plastic materials--Part 1: Feedstock materials.	ISO/ASTM 52903-1 First edition 2020-04.
8-554	Additive manufacturing--Design--Functionally graded additive manufacturing.	ISO/ASTM TR 52912 First edition 2020-09.

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
J. Nanotechnology		
18-17	Nanotechnologies--Measurements of particle size and shape distributions by transmission electron microscopy.	ISO 21363 First edition 2020-06.
18-18	Standard Test Method for Measuring the Size of Nanoparticles in Aqueous Media Using Dynamic Light Scattering.	ASTM E3247-20.
K. Neurology		
17-17	Standard Specification for Neurosurgical Head Holder Devices.	ASTM F3395/F3395M-19.
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)		
No new entries at this time.		
M. Ophthalmic		
10-121	Ophthalmic implants--Ocular endotamponades.	ISO 16672 Third edition 2020-06.
N. Orthopedic		
No new entries at this time.		
O. Physical Medicine		
16-230	American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 25: Batteries and Chargers for Powered Wheelchairs.	ANSI/RESNA WC-2:2019 Section 25.
P. Radiology		
No new entries at this time.		
Q. Software/Informatics		
13-116	Common Vulnerability Scoring System version 3.0.	FIRST CVSS v3.0.
R. Sterility		
No new entries at this time.		
S. Tissue Engineering		
No new entries at this time.		

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. Such standards are those that FDA has recognized by notice published in the *Federal Register* or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the *Federal Register*). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the *Federal Register* once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to CDRHStandardsStaff@fda.hhs.gov. To be considered, such

recommendations should contain, at a minimum, the information available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.

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Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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